Receipt date: 06/01/2006

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IFW

Docket No.: 0152-0725PUS1

Examiner: Not Yet Assigned

(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of: Noboru FUKUDA et al.		
Application No.: 10/570,159	/	Confirmation No.: N/A
Filed: March 1, 2006		Art Unit: N/A

INFORMATION DISCLOSURE STATEMENT (SUBMISSION AFTER FILING OF AN APPLICATION BUT BEFORE FINAL REJECTION OR NOTICE OF ALLOWANCE OR CONCURRENTLY WITH A RULE 1.114 RCE APPLICATION)

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

For: TGF-β GENE EXPRESSION INHIBITOR

Sir:

Pursuant to 37 C.F.R. §§ 1.97 and 1.98, applicant(s) hereby submit(s) an Information Disclosure Statement for consideration by the Examiner.

I. LIST OF PATENTS, PUBLICATIONS OR OTHER INFORMATION

The patents, publications, or other information submitted for consideration by the Office are listed on the PTO-SB08(s), attached hereto.

II. COPIES

\boxtimes	a.	Copies of cited U.S. patents and patent application publications are not included
Copies	of fore	gn patent documents and non-patent literature are included.

	b.	Some or all of the documents listed on the PTO-SB08 are not enclosed because they
were	cited	in the International Search Report and copies should already be in the PTO file. If copies
are n	eeded	, please contact the undersigned.

Birch, Stewart, Kolasch & Birch, LLP GMM/JMK/ta

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c. <u>REFERENCES PREVIOUSLY CITED OR SUBMITTED</u> - Pursuant to 37 C.F.R. §1.98(d), consideration of information listed on the PTO-SB08 form(s) is requested since any patents, publications, or other information which are listed on the PTO-SB08 form(s) but for which copies are not enclosed herewith, were previously cited by or submitted to the PTO in one of the following applications which has been relied upon for an earlier filing date under 35 U.S.C. § 120:

U.S. Appl. No(s) and U.S. Filing Date

III. CONCISE EXPLANATION OF THE RELEVANCE

(check at least one box)

- a. <u>DOCUMENTS IN THE ENGLISH LANGUAGE</u> The patents, publications, or other information listed on the attached PTO SB08 are in the English language and therefore, do not require a statement of relevancy.
- b. <u>DOCUMENTS NOT IN THE ENGLISH LANGUAGE</u> A concise explanation of the relevance of all patents, publications, or other information listed that is not in the English language is as follows: English abstracts are attached for JP 3045706, WO 03/000683, and JP 2001-136974. Watanabe et al., Gendaiiryo, Vol. 35, No. 2, 2003, pp.86-91, with Partial English translation, Makino N. et al., Gendaiiryo, Vol. 35, No. 2, 2003, pp. 111-116, with Partial English translation, and Fukuda, Gene Therapy for Arterial Proliferative Diseases and Progressive Renal Diseases by Nucleic Acid Medicines, Vol. 62, No. 7, pp.329-336, 2003.
- c. <u>ENGLISH LANGUAGE SEARCH REPORT</u> An English language version of the search report or action that indicates the degree of relevance found by the foreign office is attached, thereby satisfying the requirement for a concise explanation. See MPEP 609(III)(A)(3).
- d. OTHER The following additional information is provided for the Examiner's consideration. WO 02/08468 was cited in a previous Information Disclosure Statement dated March 1, 2006.
- IV. <u>FEES</u> (check one box)

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Application No.: 10/570,159 Docket No.: 0152-0725PUS1 This Information Disclosure Statement is being filed concurrently with the filing of a a. new patent application; therefore, no fee is required. This Information Disclosure Statement is being filed concurrent with the filing of a b. continuation-in-part, continuation, or divisional patent application; therefore, no fee is required. \boxtimes This Information Disclosure Statement is being filed within three months of the filing c. date of a national application (37 C.F.R. § 1.97(b)(1)). No fee or statement is required. (This section is not to be used with RCE's.) This Information Disclosure Statement is being filed within three months of the date d. of entry of the national stage as set forth in § 1.491 in an international application (37 C.F.R. § 1.97(b)(2)). No fee or statement is required. This Information Disclosure Statement is being filed concurrently with the filing of a Request for Continued Examination under § 1.114 (37 C.F.R. § 1.97(b)(4)). No fee or statement is required. f. This Information Disclosure Statement is being filed before the mailing date of a first Action on the merits (37 C.F.R. § 1.97(b)(3)). No fee or statement is required. In the event that a first Office Action on the merits has been issued, please consider this IDS under 37 C.F.R. § 1.97(c) and see the statement under 37 C.F.R. § 1.97(e) below, or, if no statement has been made, charge our deposit account for the fee as required by 37 C.F.R. § 1.17(p). This Information Disclosure Statement is being filed before the mailing date of a g. Final Office Action under 37 C.F.R. § 1.113 (See 37 C.F.R. § 1.97(c)(1)) or before the mailing date of a Notice of Allowance under 37 C.F.R. § 1.311 (See 37 C.F.R. § 1.97(c)(2)). No statement; therefore, a fee as required by 37 C.F.R. § 1.17(p) is attached. or

See the statement below. No fee is required.

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V.	STATE	EMENT UNDER 37 C.F.R. § 1.97(e)
	(check	only one box)
	The unc	dersigned hereby states that:
		Each item of information contained in the IDS was first cited in any
commu	ınicatio	n from a foreign Patent Office in a counterpart foreign application not more
than 30) days p	orior to the filing of this IDS; or
	b.	Each item of information contained in the IDS was first cited in any communication
from a	foreign	Patent Office in a counterpart foreign application not more than three months prior to
the filin	ng of thi	s IDS; or
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•		Office in a counterpart foreign application, and, to the knowledge of the person
		ertification after making reasonable inquiry, no item of IDS was known to any
individ	ual desig	gnated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of the IDS.
	d.	Some of the items of information were cited in a communication from a foreign
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in the I	DS was	first cited in a communication from a foreign Patent Office in a counterpart foreign
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informa	ation, th	e undersigned hereby states that no item of this remaining information contained in
		cited in a communication from a foreign Patent Office in a counterpart foreign
		i, to the best of my knowledge after making reasonable inquiry, was known to any
		ignated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this
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VI.	<u>PAYM</u>	ENT OF FEES (check one box)
		The required fee is listed on the attached Fee Transmittal.
	\boxtimes	No fee is required.

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If the Examiner has any questions concerning this IDS, he/she is requested to contact the undersigned. If it is determined that this IDS has been filed under the wrong rule, the PTO is requested to consider this IDS under the proper rule and charge the appropriate fee to Deposit Account No. 02-2448.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

Dated:

Respectfully submitted,

Gerald M. Myrphy, Jr. Registration No.: 28,977

BIRCH, STEWART, KOLASCH & BIRCH, LLP

8110 Gatehouse Road

Suite 100 East P.O. Box 747

Falls Church, Virginia 22040-0747

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Attorney for Applicant

Attachment(s):

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Documents

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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of

Complete if Known			
Application Number 10/570,159			
Filing Date March 1, 2006			
First Named Inventor Noboru FUKUDA			
Art Unit N/A			
Examiner Name Not Yet Assigned			
Attorney Docket Number	0152-0725PUS1		

	U.S. PATENT DOCUMENTS				
Examiner Initials*	Cite No.1	Document Number Number-Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear

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	FOREIGN PATENT DOCUMENTS					
Examiner	Cite	Foreign Patent Document	Publication Date	Name of Patentee or	Pages, Columns, Lines, Where Relevant Passages	
Initials*	No.1	Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)		Applicant of Cited Document	or Relevant Figures Appear	78
	BA	JP-3045706-B1	03-17-2000			
	BB	JP-2001-136974-A	05-22-2001			
	вс	WO-03/000683-A1	01-03-2003			

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§ Applicant is to place a check mark here if English language Translation is attached.

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	CA	Piek et al., FASEB J., Vol. 13, No. 15, pp.2105-2124, 1999	
	СВ	Bataller R. et al., Gastroenterology, Vol. 118, No. 6, 2000, pp. 1149-1156	
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	CD	YamamotoT. et al., Kidney International, Vol. 49, No. 2, 1996, pp.461-469	
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	CI	Mori et al., Journal of Cellular Physiology, Vol. 181, pp.153-159, 1999	
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	CU	Lee et al., Proc. Natl. Acad. Sci. USA, Vol. 93, pp.2570-2575, 1996	
	CV	Dickinson et al., Biochemistry, Vol. 38, pp.10801-10807, 1999	
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	CX	Fukuda, Gene Therapy for Arterial Proliferative Diseases and Progressive Renal Diseases by Nucleic Acid Medicines, Vol. 62, No. 7, pp.329-336, 2003	

Date Examiner Considered Signature

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Filing Date	March 1, 2006		
First Named Inventor	Noboru FUKUDA		
Art Unit N/A			
Examiner Name Not Yet Assigned			
Attorney Docket Number	0152-0725PUS1		

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CA1	Hu et al., Journal of Hypertension, Vol. 19, No. 2, pp. 203-212, 2001	
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CU1	Kozak, Annu. Rev. Cell Biol., Vol. 8, pp. 197-225, 1992	
CV1	Gottesfeld et al., Journal of Molecular Biology, Vol. 321, pp. 249-263, 2002	
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^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Examiner Signature	/Thomas Heard/	Date Considered	08/24/2009

^{&#}x27;Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.